

Office Action Summary

Application No.

10/552,459

Applicant(s)

TURIN; LUCA

Examiner

Taofiq A. Solola

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-28 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks adequate support for the claims. The term "derivative", line 1, claim 1, is not defined in the specification so as ascertain the structures of compounds that are included and/or excluded by the claims. One must read the specification into the claims, contrary to several courts' decision and Office practice, to determine a limited scope of the compounds embraced by derivative. Even then, it is not possible to ascertain the structure of all the compounds that are included and/or excluded by the term.

There are many known compounds having all the properties recited in claim 1 that are not aromachemicals, and there is no conclusive evidence in the specification that this is not true. For example, the compounds of Mustafa et al., Tetrahedron, (1965), Vol. 21, pp. 849-859, have the recited properties but are not known aromachemicals. By deleting the claims the rejection would be overcome.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for benzo[4,5]thieno[3,2b]pyran-2-one, does not reasonably

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provide enablement for compounds of claims 1-20. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

“In the context of determining whether sufficient “utility as a drug, medicant, and the like in human therapy” has been alleged, it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities] as obviously correct.” *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965). “A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), *Id.* at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel*, 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973). Where there is “no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement.” *In re Rasmusson*, 75 USPQ2d 1297 (CAFC 2005). The claimed utilities are not enabled for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

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"The factors to be considered [in making an enablement rejection] have been summarized as a) the breadth of the claims, b) the nature of the invention, c) the state of the prior art, d) the relative skill of those in that art, e) the predictability or unpredictability of the art, f) the amount of direction or guidance presented, g) the presence or absence of working examples, h) the quantity of experimentation necessary. The breathe of claims 1-20 encompass many compounds with the properties cited in claim 1. The nature of the invention is in pharmaceutical aromatics. Applicant claims all compounds having the cited properties in claim 1. However, the specification discloses only benzo[4,5]thieno[3,2b]pyran-2-one as aromatic.

There is no prior art claiming all compounds with the cited properties that are aromachemicals. For example, see the prior art of Mustafa et al., *supra*. Hence, there is no absolute predictability or established correlation between the claims and the example. The uncertainty presents one of ordinary skill in the art with obstacles and prevents her from accepting the claims on their face. The level of ordinary skill in the art of pharmaceutical aromatics is high. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Given the limited guidance in the specification one of ordinary skill in the art would have to perform significant amount of experiments, starting from the first to the last page of an organic chemistry textbook and trying every compound that meets the descriptions of compounds in claim 1 to determine which ones are applicable in the instant invention.

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the

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claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27

USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For reasons set forth above under 35 USC 112, first paragraph, claims 1-20 are indefinite. Also, it is not possible to ascertain the metes and bounds of the claims.

Claim 24 is confusing and therefore indefinite. It is not clear what applicant is claiming.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Mustafa et al., Tetrahedron, (1965), Vol. 21, pp. 849-859.

Mustafa et al., disclose compounds IV, VII, VIII and X at pages 851-854. The instant compounds are claimed with their intended use as aromachemicals. Under the US patent practice intended use is not a limitation of a compound or product. *In re Hack*, 114USPQ 161 (CCPA, 1957); *In re Craig*, 90 USPQ 33 (CCPA, 1951); *In re Brenner*, 82 USPQ 49 (CCPA, 1949).

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Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Boggle et al., Monatshefte fur Chemie (1988), Vol. 119, pp. 945-951.

Boggle et al., disclose benzo[4,5]thieno[3,2b]pyran-2-one (compound Ic) and composition thereof at pages 946; 947, lines 12-13; 948, line 19. The instant compounds and compositions are claimed with their intended use as aromachemicals. Under the US patent practice intended use is not a limitation of a compound or product. *In re Hack*, 114USPQ 161 (CCPA, 1957); *In re Craig*, 90 USPQ 33 (CCPA, 1951); *In re Brenner*, 82 USPQ 49 (CCPA, 1949).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boggle et al., Monatshefte fur Chemie (1988), Vol. 119, pp. 945-951.

Applicant claims compounds having properties cited in claim 1, their compositions with intended use as cosmetics. In preferred embodiments, the compound is benzo[4,5]thieno[3,2b]pyran-2-one, the composition comprise variable amounts of the active compound or additional active compound.

Determination of the scope and content of the prior art (MPEP 2141.01)

Boggle et al., teach benzo[4,5]thieno[3,2b]pyran-2-one (compound Ic) and composition thereof at pages 946; 947, lines 12-13; 948, line 19. The composition comprises additional active compounds. Compound Ic is within the scope of compounds described in claim 1.

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Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Boggle et al., is that applicant claims compositions with intended use, and variable amounts of the active compounds.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, it is well known in the cosmetics industries to use variable amounts of the active compounds. See US 3,779,932; 3,947,574; 4,055,634 and 4,708,821. Under the US patent practice intended use is not a limitation of a compound or product. *In re Hack*, 114USPQ 161 (CCPA, 1957); *In re Craig*, 90 USPQ 33 (CCPA, 1951); *In re Brenner*, 82 USPQ 49 (CCPA, 1949). Therefore, the instant invention is prima facie obvious from the teaching of Boggle et al. One of ordinary skill in the art would have known to make compositions having variable amounts of the active compound at the time the invention was made. The motivation is from the well-known practice in the cosmetics industries of doing such.

Also, the addition of an inert carrier to a non-patentable compound is unpatentable, *In re Best*, 195 USPQ 430 (CCPA 1977), and changing the amounts of the active compound in a composition does not rise to the level of invention under the US patent practice. If applicant discovered a new use for the compound of Boggle et al, applicant is entitled to apply for such.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



ITAOFIQ SOLOLA
PRIMARY EXAMINER

Group 1625

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